General

Guideline Title

Guideline for processing flexible endoscopes.

Bibliographic Source(s)

Van Wicklin SA, Conner R, Spry C. Guideline for processing flexible endoscopes. In: 2016 Guidelines for Perioperative Practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2016 Feb. p. 675-758. [418 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the Association of periOperative Nurses (AORN): This document provides guidance to perioperative, endoscopy, and sterile processing personnel for processing all types of reusable flexible endoscopes and accessories. Recommendations are provided for design and construction of the endoscopy suite as well as for controlling and maintaining the environment to support processing activities. Guidance is provided for maintaining records of processing for traceability and for quality assurance measures related to processing flexible endoscopes and accessories.

I. Flexible endoscopes should be processed in an area designed and constructed to support processing activities (Alvarado & Reichelderfer, 2000; "Guidelines for design and construction", 2014; "ANSI/AAMI ST91", 2015; Health Service Executive Advisory Group [HSE], 2012; "Clarification", 2012; "Infection control in endoscopy", 2010; Society of Gastroenterology Nurses and Associates, 2013; Hookey et al., 2013; Du Rand et al., 2013; World Gastroenterology Organization/World Endoscopy Organization, 2015).
II. Flexible endoscopes should be processed in an area controlled and maintained to support processing activities (Alvarado & Reichelderfer, 2000; "Guidelines for design and construction", 2014; "ANSI/AAMI ST91", 2015; HSE, 2012; "Clarification", 2012; "Infection control in endoscopy", 2010; Society of Gastroenterology Nurses and Associates, 2013; Hookey et al., 2013; Du Rand et al., 2013; World Gastroenterology Organization/World Endoscopy Organization, 2015; "Choice framework", 2013).
III. Flexible endoscopes and accessories should be precleaned at the point of use.
IV. After precleaning at the point of use, contaminated flexible endoscopes and accessories should be transported to the endoscopy processing room.
V. Flexible endoscopes designed to be leak tested, should be leak tested after each use, after any event that may have damaged the endoscope, and before use of a newly purchased, repaired, or loaned endoscope.
VI. After leak testing and before high-level disinfection or sterilization, flexible endoscopes should be manually cleaned.

VII. Flexible endoscopes, accessories, and associated equipment should be visually inspected for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.
VIII. After manual cleaning and inspection, flexible endoscopes and endoscope accessories should be high-level disinfected or sterilized (Rutala & Weber, 2008).
IX. Flexible endoscopes and endoscope accessories should be stored in a manner that minimizes contamination and protects the device or item from damage (Alvarado & Reichelderfer, 2000; "ANSI/AAMI ST91", 2015; HSE, 2012; Society of Gastroenterology Nurses and Associates, 2013; ASGE Quality Assurance In Endoscopy Committee et al., 2011; Rutala & Weber, 2008; Rudy, Adams, & Waddington, 2012; Clemens et al., 2010).
X. The health care organization should maintain records of flexible endoscope processing and procedures.
XI. Personnel with responsibility for processing flexible endoscopes should receive initial and ongoing education and complete competency verification activities related to processing flexible endoscopes.
XII. Policies and procedures for processing flexible endoscopes should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting in which they are used.
XIII. The health care organization's quality management program should evaluate processing of flexible endoscopes.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Any condition requiring procedures in which flexible endoscopes are used

Guideline Category

Management

Prevention

Risk Assessment

Clinical Specialty

Nursing

Surgery

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Guideline Objective(s)

- To provide guidance to perioperative, endoscopy, and sterile processing personnel for processing all types of reusable flexible endoscopes and accessories

- To provide guidance for design and construction of the endoscopy suite as well as for controlling and maintaining the environment to support processing activities
- To provide guidance for maintaining records of processing for traceability and for quality assurance measures related to processing flexible endoscopes and accessories

Target Population

Patients undergoing endoscopic procedures in which flexible endoscopes are used

Interventions and Practices Considered

1. Processing of flexible endoscopes in appropriately designated areas
2. Precleaning of flexible endoscopes and accessories at the point of use
3. Transporting contaminated flexible endoscopes and accessories after precleaning at the point of use
4. Leak testing of flexible endoscopes
5. Manual cleaning of flexible endoscopes after leak testing and before high-level disinfection or sterilization
6. Visual inspection of flexible endoscopes, accessories, and associated equipment
7. High-level disinfection or sterilization of flexible endoscopes and endoscope accessories
8. Storage of flexible endoscopes and endoscope accessories to minimize contamination and damage
9. Maintenance of endoscope processing and procedures records by health care organization
10. Education and competency verification activities related to processing flexible endoscopes
11. Development of policies and procedures for processing flexible endoscopes
12. Evaluation of flexible endoscope processing by the health care organization's quality management program

Major Outcomes Considered

- Risk of patient-to-patient transmission of infections via flexible endoscopes
- Cost of care
- Number of repairs and repair costs
- Presence or absence of bacteria and fungi on endoscopes (positive/negative cultures, log reduction of colony-forming units [CFUs], presence of biofilm)
- Compliance with guidelines, recommendations, and policies
- Amount and types of soil remaining on endoscopes
- Validity of benchmark levels of protein, bioburden and adenosine triphosphate (ATP)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence Review

A medical librarian conducted a systematic search of the databases Ovid MEDLINE®, EBSCO Cumulative Index to Nursing and Allied Health Literature (CINAHL®), and Scopus® as well as of the Ovid Cochrane Database of Systematic Reviews. Search results were limited to literature

published in English from 1994 through 2014. At the time of the initial search, the librarian established weekly alerts on the search topics and until October 2015, presented relevant results to the lead author. The author and the librarian also identified relevant guidelines and guidance from government agencies, professional organizations, and standards-setting bodies. Finally, during the development of this guideline, the author requested supplementary searches for topics not included in the original search as well as articles and other sources that were discovered during the evidence-appraisal process.

Search terms included the subject headings *endoscopes, disinfection, decontamination, sterilization, disinfectants, detergents, biofilms, infection control, cross-infection, equipment contamination, occupational exposure, protective clothing,* and *hypersensitivity*. Subject headings and key words for specific types of endoscopes, bacteria, disinfectants, and protective devices also were included, as were headings and terms related to the concepts of endoscope storage, methods of reprocessing, disinfection monitoring, infection transmission, disposable and reusable equipment, occupational allergies and injuries, and air pollution and ventilation. Complete search strategies are available upon request.

Excluded were non-peer-reviewed or retracted publications and evidence specific to the mechanism of action or health hazards associated with specific high-level disinfectants or liquid chemical sterilants, rigid endoscopic instrumentation, endoscopic medical treatment protocols, techniques, patient management, or functional design of flexible endoscopes.

Number of Source Documents

In total, 1,257 research and non-research sources of evidence were identified for possible inclusion. 418 full-text sources were cited in the guideline. See Figure 2 in the original guideline document for a flow diagram of literature search results.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

I: Randomized controlled trial (RCT) or experimental study, systematic review of all RCTs

II: Quasi-experimental study, systematic review of quasi-experimental studies or combination of quasi-experimental and RCTs

III: Non-experimental studies, qualitative studies, systematic review of non-experimental studies, combination of non-experimental, quasi-experimental, and RCTs, or any or all studies are qualitative

IV: Clinical practice guidelines, position or consensus statements

V: Literature review, expert opinion, case report, community standard, clinician experience, consumer experience, organizational experience (quality improvement, financial)

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Articles identified by the search were provided to the lead author and an evidence appraiser. The lead author and evidence appraiser reviewed and critically appraised each article using the Association of periOperative Registered Nurses (AORN) Research or Non-Research Evidence Appraisal Tools as appropriate. The literature was independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score. The appraisal score is noted in brackets after each reference, as applicable, in the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The collective evidence supporting each intervention within a specific recommendation was summarized and the Association of periOperative Registered Nurses (AORN) Evidence Rating Model (see the "Rating Scheme for the Strength of the Recommendations" field) was used to rate the strength of the evidence. Factors considered in the review of the collective evidence were the quality of the evidence, the quantity of similar evidence on a given topic, and the consistency of evidence supporting a recommendation. The evidence rating is noted in brackets after each intervention in the original guideline document.

Rating Scheme for the Strength of the Recommendations

1: Strong Evidence: Interventions or activities for which effectiveness has been demonstrated by high quality evidence from rigorously-designed studies, meta-analyses, or systematic reviews, or rigorously-developed clinical practice guidelines

- Evidence from a meta-analysis or systematic review of research studies that incorporated evidence appraisal and synthesis of the evidence in the analysis
- Supportive evidence from a single well-conducted randomized controlled trial (RCT)
- Guidelines that are developed by a panel of experts, that derive from an explicit literature search methodology, and include evidence appraisal and synthesis of the evidence

1: Regulatory Requirement: Federal law or regulation.

2: High Evidence: Interventions or activities for which effectiveness has been demonstrated by evidence from:

- Good quality systematic review of RCTs
- High quality systematic review in which all studies are quasi-experimental or a combination of RCTs and quasi-experimental studies
- High quality quasi-experimental study
- High quality systematic review in which all studies are non-experimental or include a combination of RCTs, quasi-experimental, and non-experimental studies. Any or all studies may be qualitative
- High quality non-experimental studies
- High quality qualitative studies
- Good quality clinical practice guideline, consensus or position statement

3: Moderate Evidence: Interventions or activities for which the evidence is has been demonstrated by evidence from:

- Good quality systematic review in which all studies are quasi-experimental or a combination of RCTs and quasi-experimental studies
- Good quality quasi-experimental study
- High or good quality literature review, case report, expert opinion, or organizational experience

4: Limited Evidence: Interventions or activities for which there are currently insufficient evidence or evidence of low quality

- Supportive evidence from a poorly conducted research study
- Evidence from non-experimental studies with high potential for bias
- Guidelines developed largely by consensus or expert opinion
- Non-research evidence with insufficient evidence or inconsistent results
- Conflicting evidence, but where the preponderance of the evidence supports the recommendation

5: Benefits Balanced with Harms: Selected interventions or activities for which the Association of periOperative Registered Nurses (AORN) Guidelines Advisory Board is of the opinion that the desirable effects of following this recommendation outweigh the harms

Cost Analysis

The guideline developers reviewed published cost analyses, including studies of endoscope damage and repair costs, costs of personnel resources

and consumable supplies associated with mechanical processors, and costs of disinfection practices. See the original guideline document for summaries of these cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The Guideline for Processing Flexible Endoscopes has been approved by the Association of periOperative Registered Nurses (AORN) Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective February 1, 2016.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. Association for Professionals in Infection Control. Am J Infect Control. 2000 Apr;28(2):138-55. PubMed

ANSI/AAMI ST91: 2015 flexible and semi-rigid endoscope processing in health care facilities. Arlington (VA): Association for the Advancement of Medical Instrumentation (AAMI); 2015.

ASGE Quality Assurance In Endoscopy Committee, Petersen BT, Chennat J, Cohen J, Cotton PB, Greenwald DA, Kowalski TE, Krinsky ML, Park WG, Pike IM, Romagnuolo J, Society for Healthcare Epidemiology of America, Rutala WA. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011. Gastrointest Endosc. 2011 Jun;73(6):1075-84. PubMed

Choice framework for local policy and procedures 01-06â€"decontamination of flexible endoscopes: policy and management. [internet]. UK Department of Health; 2013 [accessed 2015 Dec 09]. [23].

CLARIFICATION: requirements for an endoscopy equipment processing room. Jt Comm Perspect. 2012 Mar;32(3):13-4. PubMed

Clemens JQ, Dowling R, Foley F, Goldman HB, Gonzalez CM, Tessier C, Wasner MA, Young E, American Urological Association, Society of Urologic Nurses and Associates. Joint AUA/SUNA white paper on reprocessing of flexible cystoscopes. J Urol. 2010 Dec;184(6):2241-5. PubMed

Du Rand IA, Blaikley J, Booton R, Chaudhuri N, Gupta V, Khalid S, Mandal S, Martin J, Mills J, Navani N, Rahman NM, Wrightson JM, Munavvar M, British Thoracic Society Bronchoscopy Guideline Group. British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults. Thorax. 2013 Aug;68(Suppl 1):i1-44. [303 references] PubMed

Guidelines for design and construction of hospitals and outpatient facilities. Chicago (IL): Facility Guidelines Institute; 2014.

Health Service Executive Advisory Group. HSE standards and recommended practices for endosope reprocessing units. Tipperary (Ireland): HSE; 2012.

Hookey L, Armstrong D, Enns R, Matlow A, Singh H, Love J. Summary of guidelines for infection prevention and control for flexible

gastrointestinal endoscopy. Can J Gastroenterol. 2013 Jun;27(6):347-50. PubMed

Infection control in endoscopy. 3rd ed. Victoria (Australia): Gastroenterological Society of Australia and the Gastroenterological Nurses College of Australia; 2010.

Rudy SF, Adams J, Waddington C. Implementing the SOHN-endorsed AORN guidelines for reprocessing reusable upper airway endoscopes. ORL Head Neck Nurs. 2012 Dec;30(1):6-15.

Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2008. 158 p.

Society of Gastroenterology Nurses and Associates. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. Gastroenterol Nurs. 2013 Jul-Aug;36(4):293-303. PubMed

World Gastroenterology Organisation/World Endoscopy Organization. Endoscope disinfection - a resource-sensitive approach. [internet]. World Endoscopy Organisation; [accessed 2015 Dec 09]. [14].

Type of Evidence Supporting the Recommendations

The literature was independently evaluated and appraised according to the strength and quality of the evidence. Each article was when assigned an appraisal score. The appraisal score is noted in brackets after each reference, as applicable. Also see the original guideline document for the systematic review and discussion of evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- The risk of patient-to-patient transmission of infection via flexible endoscopes will be reduced.
- Refer to the original guideline document for additional discussion of potential benefits of specific interventions.

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- These recommendations represent the Association's official position on questions regarding optimal perioperative nursing practice.
- No attempt has been made to gain consensus among users, manufacturers, and consumers of any material or product.
- Compliance with the Association of periOperative Registered Nurses (AORN) guideline is voluntary.
- AORN's recommendations are intended as achievable and represent what is believed to be an optimal level of patient care within surgical and invasive procedure settings.
- Although they are considered to represent the optimal level of practice, variations in practice settings and clinical situations may limit the degree to which each recommendation can be implemented.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Feb

Guideline Developer(s)

Association of periOperative Registered Nurses - Professional Association

Source(s) of Funding

Association of periOperative Registered Nurses (AORN)

Guideline Committee

Association of periOperative Registered Nurses (AORN) Guidelines Advisory Board

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Financial Disclosures/Conflicts of Interest

No financial relationships relevant to the content of this guideline have been disclosed by the authors, planners, peer reviewers, or staff.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available to subscribers from the Association of periOperative Nurses Web (AORN) site .

Print copies: Available for purchase from the AORN Web site .

Availability of Companion Documents

The following is available:

- Guideline for processing flexible endoscopes evidence table. 2016. 51 p. Available from the Association of periOperative Nurses (AORN) Web site .

Additional implementation tools, including clinical FAQs, online learning modules, videos and community discussions are available from the AORN Web site .

Documents related to the evidence rating model, hierarchy of evidence, and expanded appraisal tools are available from the AORN Web site.

In addition, an AORN Guidelines for Perioperative Practice eBook mobile app is available from the AORN Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 17, 2016. The information was verified by the guideline developer on March 30, 2016.

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